DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Carestream Health, Inc.
% Ms. Carolyn Wagner
Regulatory Affairs Manager
150 Verona Street
ROCHESTER NY 14608

March 11, 2015

Re: K141837
Trade/Device Name: DRX-Evolution
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: February 21, 2015
Received: February 24, 2015

Dear Ms. Wagner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141837

Device Name: DRX-Evolution

Indications for Use:
The device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging including tomography. The tomography feature is not to be used for imaging pediatric patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K141837

Carestream

"510(k) Summary"

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, New York 14608
510(k) Owner Phone:	585-627-6588
510(k) Owner Fax:	585-323-7643
Contact Person & Info:	Carolyn Wagner Sr. Regulatory Affairs Manager, X-Ray Systems carolyn.wagner@carestreamhealth.com 585-627-6588
Date Summary Prepared:	March 10, 2015
Device Trade Name:	Carestream DRX-Evolution
Device Common Name:	diagnostic x-ray system
Classification Name:	Stationary x-ray system
Device Class:	Class II
Device (Product) Code:	KPR
Regulation Number:	21 CFR 892.1680
Predicate Device:	Carestream DRX-Evolution Manufactured by Carestream Health, Inc. 510(k) No. K091889 (July 20, 2009) Regulation No. 21 CFR 892.1680 Product Code: KPR
Reference Device:	Tomo-Link Manufactured by GE Medical Systems 510(k) No. K944967 (12/09/1994) Regulation No. 21 CFR 892.1740 Product Code: IZF

Device Description:
The DRX-Evolution is a diagnostic x-ray system utilizing digital radiography (DR) technology. The DRX-Evolution is designed for horizontal and upright projection exams. The system consists of a high voltage x-ray generator, overhead tube crane with

x-ray tube assembly, radiographic table with detector tray, Bucky image receptor on an upright wall stand, and x-ray controls containing a power distribution unit and operator PC (user interface).
The modifications to the device described in this submission include firmware and mechanical changes to facilitate use of the device for linear tomography exams and addition of a new generator option. Software updates to the DRX-Evolution include features such as Bone Suppression, Pneumothorax Visualization, and the ability to integrate the DRX-1C and DRX 2530C Detectors.

The new alternate generator has been implemented as an option for use with the DRX-Evolution system. Implementation of the new optional generator is transparent to the user and does not require any update to the user interface. The new generator is functionally equivalent to the generator cleared under the original 510(k) for this device.

The modifications to the DRX-Evolution device raise no new issues of safety or effectiveness.

Indications for Use / Intended Use:
The Indications for Use for the modified device, as described in its labeling, are: "The device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging including tomography. The tomography feature is not to be used for imaging pediatric patients." The Indications for Use for the modified device are similar to the originally cleared DRX-Evolution (predicate device) except for the addition of the tomography functionality that is not to be used for pediatric patients.

The intended use for the modified device, as determined by descriptions and the proposed labeling contained in this submission, is similar to the Indications for Use statement provided above. The linear tomography exam is considered a general radiography exam and is normally performed using a stationary x-ray system such as the DRX-Evolution. This exam requires accurate movement of the x-ray tube head with respect to the image capture device (and patient). This functionality is similar to the existing long length imaging function of the DRX-Evolution that controls accurate movement of the tube head and detector with respect to the patient.

Comparison of Technological Characteristics:
The modified DRX-Evolution device has the same technological characteristics as the originally cleared DRX-Evolution predicate device (K091889). In addition, firmware and hardware have been modified to enable accurate synchronized movement of the flat panel imager in the table with respect to movement of the tube head to add linear tomography functionality. Other added features such as the optional generator and new software options do not introduce new technological characteristics and are briefly described below.

Implementation of the alternative (optional) generator is transparent to the user and does not require changes to the existing selections pertaining to the generator available on the system console user interface.

The capability to perform linear tomography exams employs similar technology to the long length imaging feature that ensures proper synchronization of the tube head and detector for long length imaging exams. A longer exposure (approximately 3 seconds) is required for a linear tomography exam but the amount of radiation exposure is still within the window of some non linear tomography exams (i.e. exams for larger patients that require longer exposure to obtain a usable image).

Additional software features cleared by FDA for use on Carestream DR devices are extensions of the original image processing software incorporated in the DRX-Evolution system. These additional software features provide companion views to the original image than can be used to aid diagnosis. Incorporation of these optional features in the DRX-Evolution is consistent with its existing technological characteristics.

The DRX-Evolution can be used with the legally marketed Carestream DRX-1, DRX-1C and DRX 2530C detectors that are commercially available for use with other Carestream products or as standalone devices. The Carestream DRX-1 Detector utilizes a gadolinium oxysulfide (GOS) scintillator while the Carestream DRX-1C and DRX 2530C Detectors utilize a cesium iodide (CsI) scintillator, with all other aspects of the design and function remaining the same except for the size.

Ability to integrate Carestream's DRX-1C and DRX 2530C detectors with the DRX-Evolution required only minor updates to the user interface to select the detector being used so that exposure parameters are calculated appropriately. These detectors are functionally identical to the DRX-1 Detector except that they provide equal or superior image quality with respect to noise and spatial resolution at equivalent doses.

Discussion of Performance Testing - Bench:

The performance characteristics and operation / usability of the Carestream DRX-Evolution system were evaluated in non-clinical (bench) testing. These studies demonstrated the intended workflow, related performance, overall function, verification and validation of requirements for intended use, shipping performance, and reliability of the DRX-Evolution system including both software and hardware requirements. Non-clinical test results have demonstrated that the device conforms to its specifications. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

The linear tomography functionality was evaluated in bench testing using a tool phantom designed to evaluate this functionality, and also using anthropomorphic phantoms. Test results using the tool phantom were as expected, demonstrating accuracy of the tube head movement with respect to the capture device. In addition, linear tomography images were generated using four different anthropomorphic phantoms (chest, hand, knee and

pelvis). The images were evaluated by a board-certified radiologist for diagnostic quality. Results of this evaluation demonstrated that the linear tomography images acquired using the DRX-Evolution system are of acceptable diagnostic quality.
The tests described above and the performance data collected are consistent with the testing performed to substantiate the safety and effectiveness of linear tomography in the previously cleared reference device, Tomo-Link (K944967). The results of bench testing of new software / hardware components and phantom image evaluation of the linear tomography functionality support a substantial equivalence determination.

Discussion of Performance Testing - Clinical
Clinical studies were performed in accordance with FDA guidance document "Guidance for the Submission of 510(k)'s for Solid State Imaging Devices" to demonstrate the diagnostic capability of the DRX 2530C Detector (K130464) and DRX-1C Detector (K120062). Results of these studies demonstrated equivalent or superior image quality to the DRX-1 Detector (predicate device).

Clinical studies were also performed to evaluate the DR Long Length Imaging Software (K130567), and Bone Suppression software (K133442). Results of the DR Long Length Imaging study demonstrated that the investigational software produced LLI images with statistically equivalent or better diagnostic capability to the predicate software. Results of the Bone Suppression clinical study demonstrated that the software generates a companion image that, when presented to the physician along with the standard-of-care image, is rated substantially equivalent or improved as compared to that of the predicate product (standard-of-care image without the bone-suppressed companion image).

The results of the clinical testing described above support a substantial equivalence determination.